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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,267	12/21/2001	Dennis Stein Everhart	16,540	3116

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EXAMINER	
STEPHENS, JACQUELINE F	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,267	EVERHART ET AL.	
	Examiner	Art Unit	
	Jacqueline F. Stephens	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,12,16,18,21,22,33-43,45,47-52,54,55,59,62,63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4-11,13-15,17,19,20,23-32,44,46,53,56-58,60 and 61.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/6/05 have been fully considered but they are not persuasive.

As to the rejection of claims 1, 3, 34, 35, 42, 45, 47, 48, 50-52, 55, and 63 under 35 U.S.C. 102(b) as being anticipated by Rosenbluth et al. USPN 5074855, applicant's arguments are not persuasive. In response to applicant's arguments that 1) Rosenbluth does not have a posterior region extending to the rearwardmost aspect of the vestibule; 2) the pad 12 of the Rosenbluth patent resides primarily between the labia minora and the vestibule; and 3) no portion of the pad of the Rosenbluth device is externally disposed about the vulvar region over the labia majora, the arguments are directed to an intended use of the article. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

As to claims 3 and 43, applicant argues Rosenbluth does not include a cover having a therapeutic agent coupled to the surface. Applicant is again directed to col. 5, lines 7-11 of Rosenbluth, which discloses a therapeutic agent on a surface.

2. As to the rejection of claims 12, 15, and 21 under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth USPN 5074855 in view of Lucas AU 199941153, applicant's arguments are not persuasive. Applicant argues the Lucas application does

not disclose applying an agent to a surface of either the pad of the Rosenbluth patent or the device of the instant application. Applicant argues there is no teaching or suggestion in either reference as to why or even how one would apply an agent to a flat sheet, roll the sheet, and produce the pad of the Rosenbluth patent. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Rosenbluth provides the teaching of incorporating the agent into the pad. The examiner has relied on Lucas for a teaching of a specific type of treatment agent, which Rosenbluth does not teach. Additionally, the claimed invention is neither specific as to how the treatment agent is incorporated into the article. The limitations upon which applicant relies (i.e., how one would apply an agent to a flat sheet, roll the sheet, and produce the pad) are not recited in the rejected claim(s).

3. As to the rejection of claims 21, 22, 39, 40, 43, and 62 under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth USPN 5074855 in view Harrison et al. USPN 6086909, applicant's arguments are not persuasive. Applicant argues there is no teaching or suggestion in either reference as to why or even how one would apply an combine a vaginally-applied dysmenorrheal treatment with an incontinence pad to

achieve the device of the instant application. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Rosenbluth provides the teaching of incorporating a therapeutic agent into the pad. The examiner has relied on Harrison for a teaching of a specific type of treatment agent, one which treats dysmenorrheal. It appears applicant is suggesting dysmenorrhea can only be treated with a vaginal application. However, dysmenorrhea can be treated with an external pad, such as is taught in Brown-Skrobot USPN 5389374 (Abstract, col. 3, lines 34-43; and col. 8, lines 49-62).

4. As to the rejection of claims 1, 3, 16, 18, 36-39, 41 42, 45, 48-51, 52, 55, and 59 under 35 U.S.C. 103(a) as being unpatentable over Goldfarb et al. USPN 3490454 in view of Rosenbluth USPN 5074855; and the rejection of claim 54 under 35 U.S.C. 103(a) as being unpatentable over Goldfarb et al. USPN 3490454 in view of Rosenbluth USPN 5074855 and further in view of Karami et al. USPN 4726976, applicant's arguments are not persuasive. In response to applicant's arguments that neither the Rosenbluth nor Goldfarb patents disclose 1) a posterior region extending to the rearwardmost aspect of the vestibule; or 2) an anterior region for generally external disposition about the vulvar region over the labia majora, the arguments are directed to

an intended use of the article. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

5. Applicant argues that the combination-for-benefit has no bearing on the instant application and the device of the instant application does not seek to leave the vaginal opening unoccluded. However, the examiner has relied on the combination of Rosenbluth and Goldfarb to modify the structure of Goldfarb based on the teachings of Rosenbluth to arrive at a structure capable of performing the intended use of the claimed invention. The fact that the examiner has recognized an advantage of the combination of Rosenbluth and Goldfarb serves as motivation to modify the structure of Goldfarb.

6. As to the rejection of claim 33 under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth USPN 5074855 in view of Lucas AU 199941153 and further in view of Bowie et al. USPN 5585277, applicant's arguments are not persuasive. Applicant argues there is no teaching or suggestion in either reference as to why or even how one would add a screening method to the tampon of the Lucas application and the incontinence device of the Rosenbluth patent. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed

invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Rosenbluth provides the teaching of incorporating the agent into the pad. The examiner has relied on Lucas for a teaching of a specific type of treatment agent, which Rosenbluth does not teach and further relied on Bowie for teaching a ligand. The examiner has provided the motivation for modifying the therapeutic agent of Rosenbluth/Lucas, which is suggested by Bowie as a benefit for binding a target protein associated with a condition or disease.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 34, 35, 42, 45, 47, 48, 50-52, 55, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbluth et al. USPN 5074855

As to claims 1, 3, 42, 55, and 63, see Abstract and col. 2,lines 25-44 where Rosenbluth discloses placement of the absorbent device and col. 5, lines 7-11 where Rosenbluth teaches the device includes a therapeutic agent.

As to claim 34, see Rosenbluth col. 5, lines 7-11.

As to claim 35, Rosenbluth discloses the therapeutic agent is applied to the surface of the absorbent article. The limitation of the agent being applied before the body is constructed is directed to a process of making the article. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). MPEP 2113.

As to claims 45, 47, 48, and 50-52, Rosenbluth discloses the therapeutic agent is applied to the surface of the pad (col. 2, lines 55-57).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 12, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth USPN 5074855 in view of Lucas AU 199941153. Rosenbluth discloses an absorbent device as claimed with a medically-active composition. However, Rosenbluth is not specific as to the formulation of the treatment agent. Lucas discloses an absorbent device having an herbal preparation for the benefit of alleviating or regulating discomforts associated with menses formulated to give a slow release of the active constituents (pages 2 and 3). It would have been obvious to one having ordinary skill in the art to modify the invention of Rosenbluth with a composition as taught in Lucas for the benefits Lucas discloses.

As to claims 12 and 16, Rosenbluth/Lucas discloses the therapeutic agent is a powder, which is also a solid (Lucas page 2, lines 12-14).

As to claim 21, Rosenbluth/Lucas discloses the therapeutic agent is capable of treating dysmenorrhea (Lucas page 4, lines 7-10).

12. Claims 21, 22, 39, 40, 43, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth USPN 5074855 in view of Harrison et al. USPN 6086909. Rosenbluth discloses the present invention substantially as claimed. However, Rosenbluth does not disclose the claimed materials. Harrison discloses

formulations beneficial to the treatment of dysmenorrhea. It would have been obvious to one having ordinary skill in the art to modify Rosenbluth to include the formulations disclosed in Harrison to provide the additional benefits of treating dysmenorrhea.

As to claims 21, 39, and 40, see Harrison Abstract and col. 13, lines 34-60.

As to claim 22, Rosenbluth/Harrison discloses the claimed therapeutic agents (Harrison col. 4, lines 43-59).

As to claims 43 and 62, Rosenbluth/Harrison discloses a mucoadhesive (Harrison col. 2, lines 60-63).

13. Claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb et al. USPN 3490454 in view of Rosenbluth USPN 5074855.

As to claims 1, 3, 16, 18, 38, 42, 45, 51, 52, and 55 Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium. Goldfarb does not disclose the claimed structure. Rosenbluth discloses the claimed structure having a posterior region including a raise profile and the claimed application region for the benefit of sealing against the vestibule of a female and occluding the urethral meatus creating an effective but small device that is easy to wear (Rosenbluth col. 2, lines 25-55). It would have been obvious to one having ordinary skill in the art to modify the shape of Goldfarb with the shape of Rosenbluth for the benefit disclosed in Rosenbluth. Goldfarb/Rosenbluth teach a tampon product comprising a

fluid-absorbent body and mean for carrying a formulation including a therapeutic agent (Goldfarb col. 2, line s16-21; col. 3, lines 4-10; col. 4, lines 8-14).

As to claims 36 and 49, Goldfarb/Rosenbluth discloses the agent is located on an open or a gauze nonwoven, either of which is essentially an apertured web (Goldfarb col. 3, lines 53-54 and col. 4, lines 8-14).

As to claim 37, Goldfarb/Rosenbluth discloses the therapeutic agent is applied to creped tissue, which is well known in the art as a biodegradable material (Goldfarb col. 3, lines 34-44).

As to claim 39, Goldfarb/Rosenbluth discloses the therapeutic agent comprises a hydrogel (Goldfarb col. 6, lines 45-75).

As to claim 41, Goldfarb/Rosenbluth discloses the therapeutic agent comprises a polymeric material (Goldfarb col. 8, lines 8-38).

As to claims 48 and 50, Goldfarb/Rosenbluth discloses the agent is applied to various layers and between the layers of the absorbent product (Goldfarb col. 3, lines 34-44 and col. 4, lines 8-10). Therefore, the agent is applied before the body is completed.

As to claim 59, Goldfarb/Rosenbluth discloses delivery of the therapeutic agent is affected by melting a solid (Goldfarb col. 7, lines 1-8).

14. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth in view of Lucas and further in view of Bowie et al. USPN 5585277. Rosenbluth/Lucas discloses the present invention substantially as claimed. However, Rosenbluth/Lucas does not disclose a ligand as part of the formulation. Bowie discloses ligands can be used therapeutically to bind a target protein associated with a condition or disease, preventing or treating a condition or disease, regulate physiological function, or serve as a lead compound for identification of a therapeutically useful compound (col. 1, lines 51-60). It would have been obvious to one having ordinary skill in the art to modify the therapeutic agent of Rosenbluth/Lucas with a ligand for the benefits disclosed in Bowie.

15. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb USPN 3490454 in view of Rosenbluth USPN 5074855 and further in view of Karami et al. USPN 4726976.

As to claim 54, regarding the combination of Goldfarb and Rosenbluth, see the rejection of claim 1, paragraph 9 supra. Goldfarb/Rosenbluth discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer (Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). Goldfarb/Rosenbluth discloses the agent is located on a porous nonwoven (col. 3, lines

53-54 and col. 4, lines 8-14). However, Goldfarb/Rosenbluth does not disclose the nonwoven is a hydrophobic polymer. Karami discloses a hydrophobic coversheet for the benefit of reducing rewet (col. 6, lines 33-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb/Rosenbluth with a hydrophobic cover layer for the benefits disclosed in Karami.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacqueline F Stephens
Examiner
Art Unit 3761

November 08, 2005